



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|------------------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/665,170 | 09/18/2003 | Jaime Vargas | 144 | 6321 |
| 33109 | 7590 | 07/29/2009 | EXAMINER | |
| CARDICA, INC. | | | WOO, JULIAN W | |
| 900 SAGINAW DRIVE | | | ART UNIT | PAPER NUMBER |
| REDWOOD CITY, CA 94063 | | | 3773 | |
| | | MAIL DATE | DELIVERY MODE | |
| | | 07/29/2009 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAIME VARGAS, STEPHEN A. YENCHO, JAMEY NIELSEN,
MICHAEL HENDRICKSON and BERNARD A. HAUSEN

Appeal 2009-004039
Application 10/665,170
Technology Center 3600

Decided:¹ July 29, 2009

Before JAMESON LEE, SALLY G. LANE and MICHAEL P. TIERNEY,
Administrative Patent Judges.

TIERNEY, *Administrative Patent Judge.*

DECISION ON APPEAL

¹ The two-month period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

A. STATEMENT OF THE CASE

This is a decision on appeal by the real party in interest, Cardica, Inc. under 35 U.S.C. § 134(a) from a final rejection of claims 1-3 and 7-22. Appellants request reversal of the Examiner's rejections of claims 1-3 and 7-22. We have jurisdiction under 35 U.S.C. § 6(b). We reverse, but enter a new ground of rejection.

References Relied on by the Examiner

| | | |
|---------|-----------|--------------|
| Swanson | 6,113,612 | Sep. 5, 2000 |
| Yencho | 6,461,320 | Oct. 8, 2002 |

The Rejections on Appeal²

The Examiner rejected claims 1, 7-13, 16-20, and 22 under 35 U.S.C. § 102(e) as anticipated by Swanson.

The Examiner rejected claims 1-3, 14-15, and 21-22 under 35 U.S.C. § 102(e) as anticipated by Yencho.

Appellants argue the patentability of claim 1, but do not argue for the patentability of any of the remaining claims separately. (App. Br., 6).

The Invention

The invention relates to a method for forming an anastomosis between an end of a graft vessel and a target vessel. (Spec. ¶ 0008).³ Specifically,

² Appellants' Appeal and Reply Briefs both feature headings mentioning claims 1-15 instead of claims 1-3 and 7-22; however, the body of both briefs clearly indicate that Appellants intended to Appeal claims 1-3 and 7-22. (App. Br., 3 and 6-7; and Reply Br., 3 and 6).

³ References to the specification are to U.S. Publication 2004/0097991.

the anastomosis device utilizes a first flange attaching the graft vessel to the target vessel. (*Id.* at ¶¶ 0009-0010).

Claim 1 is illustrative of the claimed invention and is reproduced below:

1. A method of forming an anastomosis between a graft vessel and a target vessel, each vessel having a lumen therein and a wall around the lumen; the method comprising:
 - providing an anastomosis device and an expander;
 - connecting an end of the graft vessel to said anastomosis device;
 - delivering at least a portion of the anastomosis device into the lumen of the target vessel through an opening in the wall of the target vessel;
 - manipulating said anastomosis device to form a first flange therein, said first flange positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel; wherein said manipulating includes translating said expander relative to said anastomosis device, and wherein said manipulating completely forms said first flange; and
 - moving said first flange into contact with the wall of the target vessel after said manipulating is complete.

(App. Br., 8, Claims App'x.).

B. ISSUE

Have Appellants shown that the Examiner improperly determined that Swanson and Yencho teach moving a first flange into contact with the wall of a target vessel after the manipulation used to form the flange is complete?

C. FINDINGS OF FACT

Swanson

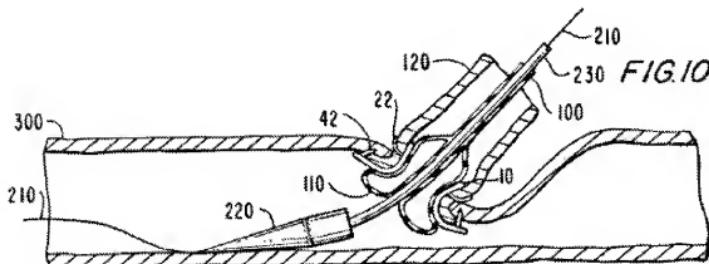
1. Swanson teaches an anastomosis device 10 for connecting the end of a

graft vessel 120 to a target vessel 300. (Swanson, col. 1, ll. 1-17; col. 7, ll. 47-63, Fig. 10).

2. Swanson teaches an anastomosis device 10, having ends that are annularly enlarged by a balloon 110 to form a first flange. (*Id.* at col. 7, ll. 47-63, col. 12, ll. 17-28).

3. Swanson's device is designed to remain in engagement with the target vessel 300 during formation of the flange. (*Id.* at col. 12, ll. 28-32, "does not slip out of engagement with the conduit 300 during annular enlargement of the connector").

4. Swanson Figure 10 depicted below shows the anastomosis device 10 while the ends of the device are being annularly enlarged by a balloon 110 to form a first flange.



Swanson Figure 10 is depicted above and shows ends of the anastomosis device 10 being annularly enlarged by a balloon 110 to form a first flange.

5. Swanson Figure 10 shows that the first flange is in contact with the target vessel 300 during the formation process. (*Id.* at Fig. 10).

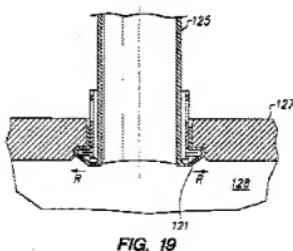
Yencho

6. Yencho discloses an anastomosis device (a stent) 110 for connecting an end of a graft vessel 125 to a target vessel 127. (Yencho, col. 10, ll. 1-3).
7. Yencho's anastomosis device 110 has a first flange 121 that is formed by application of a rotational force. (*Id.* at col. 10, ll. 34-36).
8. Yencho teaches that formation of the flange causes the stent body to longitudinally collapse. (*Id.* at col. 10, ll. 36-38).
9. Yencho discloses:

[d]uring deployment of the distal end flange, the stent body longitudinally collapses, and the distal end flange is positioned at least in part within the wall of the target vessel, so that the flange applies a force radial to the stent longitudinal axis, illustrated by the arrow R, against the wall of the target vessel defining the incision therein."

(*Id.* at col. 10, ll. 61-66).

10. Yencho Figure 19, depicted below, shows that the first flange 121 is in contact with the target vessel 127 at the time the flange is completed.



Yencho Figure 19, depicted above, shows that the first flange 121 is in contact with the target vessel 127 at the time the flange is completed.

D. PRINCIPLES OF LAW

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

E. ANALYSIS

Appellants argue dependent claims 2-3 and 7-22 collectively with claim 1, the only independent claim. The Examiner found that claim 1 was anticipated by two separate references, Swanson and Yencho. Specifically, the Examiner found that both Swanson and Yencho teach the claim limitation of “moving [the] first flange into contact with the wall of the target vessel after said manipulating [for forming the first flange] is complete.” (Ans., 3-6).

Appellants contend that neither Swanson nor Yencho specifically teach moving the first flange into contact with the wall of the target vessel after the manipulation used to form the flange is complete. (App. Br., 3-6; Reply Br., 4-5). Specifically, Appellants contend that both Swanson and Yencho teach first flanges that are already in contact with a wall of the target vessel by the time the manipulation to form the respective first flanges is complete. (App. Br., 5-6; Reply Br., 5) Accordingly, since the wall and flange are already in contact with one another, Appellants reason that the flange cannot subsequently be moved into contact with the wall, as required by the claims. (App. Br., 5-6; Reply Br., 5).

1. Anticipation Rejections based on Swanson

Swanson teaches an anastomosis device 10 for connecting the end of a graft vessel 120 to a target vessel 300. (FF 1). Swanson's anastomosis device 10 has ends that are annularly enlarged by a balloon 110 to form a first flange. (FF 2). Swanson states that the device is designed so that it "does not slip out of engagement" with the target vessel 300 during annular enlargement (formation of the flange). (FF 3). Swanson Figure 10 depicts the first flange as being in contact with the target vessel 300 during the formation process. (FF 4-5). Thus, because the flange is already in contact with target vessel, Swanson fails to teach moving the flange into contact "after" the manipulation is complete. Accordingly, Appellants have demonstrated that the Examiner improperly determined that Swanson teaches the limitation of moving a first flange into contact with the wall of the target vessel after manipulation of the flange is complete.

2. Anticipation Rejections based on Yencho

Yencho discloses an anastomosis device (a stent) 110 designed to connect one end of a graft vessel 125 to a target vessel 127. (FF 6). Yencho's anastomosis device 110 features a first flange 121 formed by the application of a rotational force. (FF 7). Yencho teaches that formation of the flange causes the stent body to longitudinally collapse. (FF 8). Particularly, Yencho discloses:

[d]uring deployment of the distal end flange, the stent body longitudinally collapses, and the distal end flange is positioned at least in part within the wall of the target vessel, so that the

flange applies a force radial to the stent longitudinal axis, illustrated by the arrow R, against the wall of the target vessel defining the incision therein.”

(FF 9). By stating that the flange applies a force to the wall of the target vessel, the above paragraph teaches that the first (distal end) flange is already in contact with the target vessel when manipulation is complete. Similarly, Yencho Figure 19, shows that the first flange 121 is already in contact with the target vessel 127 at the time the flange is completed. (FF 10). Accordingly, Appellants have demonstrated that the Examiner improperly determined that Yencho teaches the limitation of moving a first flange into contact with the wall of the target vessel after manipulation of the flange is complete.

New Ground of Rejection

Appellants have shown that the prior art fails to teach the limitation of “moving [the] first flange into contact with the wall of the target vessel after said manipulating [for forming the first flange] is complete.” (App. Br., 8, Claims App’x.). However, pursuant to our authority under 37 C.F.R. § 41.50(b), we enter a new ground of rejection for claims 1-3 and 7-22 under 35 U.S.C. § 112, first paragraph, because Appellants’ claims do not comply with the written description requirement.

Findings of Fact

The following findings of fact are supported by at least a preponderance of the evidence:

11. Appellants’ specification does not literally describe “moving said first flange into contact with the wall of the target vessel after said manipulating

is complete.”

12. Appellants’ specification does not implicitly describe “moving said first flange into contact with the wall of the target vessel after said manipulating is complete.”

13. In an Office Action dated 11/3/2006, the Examiner set forth two anticipation rejections, specifically rejecting pending claims 1, 5-13, and 16-20 as anticipated by Swanson and claims 1-3, 14-15, and 21 as anticipated by Yencho.

14. In response to the 11/3/2006 prior art rejections Appellants amended independent claim 1, the only independent claim, to include the limitation “moving said first flange into contact with the wall of the target vessel after said manipulating is complete.” (Amendment, 12/21/2006, 2).

15. Appellants stated that the added limitation of moving after manipulation is complete overcame the prior art rejections. (Amendment, 12/21/2006, 5-7).

16. Appellants’ remarks accompanying the Amendment do not identify a written description basis for the added limitation.

17. Appellants’ appeal brief, in a footnote, identifies the following portions of the specification as providing written description support for the added limitation

E.g., Specification, page 7, line 14 through page 9, line 24; page 11, line 12 through page 14, line 23; page 15, line 2 through page 18, line 14; page 19, lines 4-19; Figures 1-11, 17-18, 23-29 (exemplary reference characters indicated in text above).

(App. Br., 2-3).

18. Appellants’ brief does not explain how the above disparate portions cited for written description support would have led one of ordinary skill in

the art to conclude that Appellants necessarily possessed the claimed invention wherein the first flange is moved into contact with the wall of the target vessel “after said manipulating is complete.”

Principles of Law

The purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by the inventor. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). The inventor can demonstrate possession by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. The inventor, however, needs to show that the inventor was “in possession” of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997). Requiring possession of the invention, and not that which makes it obvious, ensures that the claimed invention does not overreach the scope of the inventor’s contribution to the field as described in the patent specification. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000).

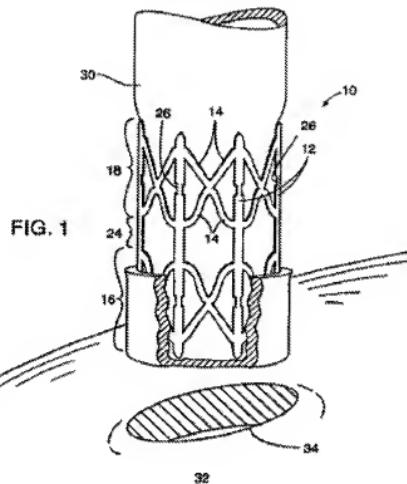
Analysis

Appellants have demonstrated that the claim limitation “moving said first flange into contact with the wall of the target vessel after said manipulating is complete” is not taught in the relied upon prior art. This limitation however, is not explicitly cited in the specification nor is it apparent how this limitation is implicitly possessed as opposed to obvious over the specification.

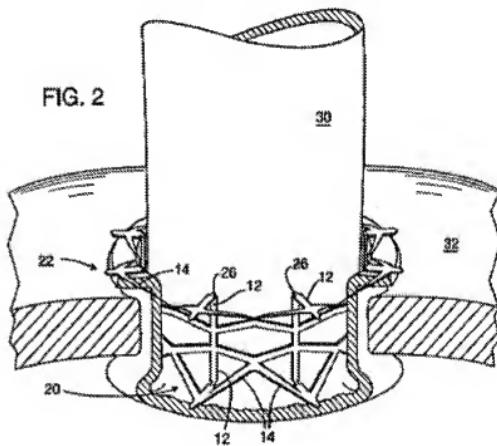
Appellants' Specification Fails to Literally or Implicitly Describe "moving said first flange into contact with the wall of the target vessel after said manipulating is complete."

Appellants' specification fails to reasonably convey to persons skilled in the art that the inventors had possession of the subject matter in question. Specifically, the specification does not literally or implicitly convey possession of a method involving moving the first flange into contact with the wall of the target vessel after the manipulation of the flange is complete.

Appellants' specification summarizes the invention as including various aspects including an embodiment directed to a method of performing anastomosis. The method involves several steps including expanding the tubular anastomosis device with an expander to cause a portion of the tube to fold outward forming a first flange and a second flange to trap a wall of the target vessel between the two flanges. (Spec., Summary of the Invention, ¶ 0010). Appellants' detailed description of the invention states that the ends of the anastomosis device are folded outward to form the first and second flanges and that once the first and second flanges have been formed the wall of the target vessel is trapped between the flanges. (Spec., Detailed Description of the Preferred Embodiments, ¶ 0046). Appellants' drawings, consistent with the specification, depict the anastomosis device prior to the formation of the flanges and again after the first and second flanges trap the vessel. For example, Appellants cited Figure 1, reproduced below, merely depicts "an anastomosis device in a configuration prior to use." (Spec., ¶ 0013).



Similarly, Appellants' Figure 2 reproduced below shows the anastomosis device "in a deployed condition." (Spec., ¶ 0014).



Appellants' written description reasonably conveys to one of ordinary skill in the art a method where a first flange is formed and then a second flange is formed thereby trapping a target vessel. Appellants' however, do not reasonably convey possession of a method where the first flange is completely formed and, after manipulation is complete, moved into contact with the wall of the target vessels.

Appellants' Remarks Regarding the Disputed Limitation Fail to Demonstrate that Appellants' Possessed the Claimed Invention as Opposed to that which makes it Obvious

Appellants did not identify the written descriptive basis for adding the moving after manipulation is complete limitation when the limitation was added by amendment on December 21, 2006. (See, FF 16). Appellants' appeal brief however, cites extensive portions of its specification (nineteen distinct drawings and portions of twelve different pages) as providing the necessary written descriptive support. (FF 17). Appellants' brief however, does not explain how these portions of the specification lead one of ordinary skill in the art to understand that the inventors possessed the claimed moving step as opposed to rendering the limitation obvious.

Appellants have failed to demonstrate that they described what has been shown on this record to be the point of novelty over the prior art. Based on our review of the record, we reject claims 1-3 and 7-22 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement.

F. CONCLUSION

Appellants have shown that the Examiner improperly determined that Swanson and Yencho teach moving a first flange into contact with the wall of a target vessel after the manipulation used to form the flange is complete?

G. ORDER

The rejections of claims 1, 7-13, 16-20, and 22 under 35 U.S.C. § 102(e) as anticipated by Swanson are reversed.

The rejections of claims 1-3, 14-15, and 21-22 under 35 U.S.C. § 102(e) as anticipated by Yencho are reversed.

In a new ground of rejection, we have rejected claims 1-3 and 7-22 under 35 U.S.C. § 112 first paragraph, failing to comply with the written description requirement.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides that “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.”

37 C.F.R. § 41.50(b) provides that Appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

- (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so

Appeal 2009-004039
Application 10/665,170

rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

ack

cc:

CARDICA, INC.
900 SAGINAW DRIVE
REDWOOD CITY CA 94063